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Dockets Management Branch
HFA-305
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

Re: Docket No. 00N-1351: Food Labeling; Use of the Term "Fresh" for Foods Processed With Alternative Non-thermal Technologies

Dear Sir or Madam:

I am writing on behalf of The Minute Maid Company ("the Company") which offers the following comments on the issues raised in the agency's July 3, 2000 Federal Register notice concerning the use of the term "fresh" on foods processed with alternative non-thermal microbial inactivation technologies (65 Fed. Reg. 41029). As explained below, the Company believes that the agency's current criteria for regulating the use of the term (criteria embodied in 21 C.F.R. § 101.95) do not need to be amended.

The Company, like many manufacturers of perishable food items, has been exploring the feasibility of adopting alternative non-thermal technologies to help ensure the production of safe products. In particular, the Company has focused on the use of ultra high pressure ("UHP") technology for the production of a safe, "fresh" orange juice. In light of this focus, our comments are offered in the context of the application of UHP technology to a food commodity like orange juice. Our comments, however, are applicable to -- and are intended to be considered in light of -- all new non-thermal technologies that not only are capable of enhancing safety of "fresh" foods but also do not affect the sensory and nutritional aspects of such foods.[1]

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[1] These technologies include but are not necessarily limited to pulsed electric field, pulsed and ultraviolet light, pulsed x-rays, oscillating magnetic field, and irradiation.

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The Agency's Initiative

In its July 3 notice, FDA advised that it wanted public comment on whether the use of the term "fresh" is truthful and not misleading on foods processed with alternative non-thermal technologies. The agency also expressed an interest in receiving comment and informed opinion regarding what type of criteria FDA should use in considering the use of the term "fresh" with new alternative technologies. In particular, the agency sought comment on how consumers and the industry view the term "fresh"; on whether the term "fresh" when applied to foods processed with new technologies could be misleading to consumers; on whether new technologies "preserve" foods or employ thermal techniques thereby precluding the use of the term "fresh"; and on whether there are quantifiable parameters that could be measured to determine whether a food subject to such technologies is, indeed, "fresh." The agency also inquired whether terms other than the word "fresh" should be used for a food to which a new technology has been applied and what the possible economic impacts of using the term "fresh" on such a food might be.

In these comments the Company responds generally to these areas of inquiry. The comments are premised on the recognition that the basis for the agency's decision to promulgate a "fresh" regulation in the first place was the longstanding agency desire to protect consumers from being misled by the deceptive use of the term "fresh." Reasoned analysis and relevant evidence support the view that the use of the term "fresh" on, for example, a UHP orange juice, falls well outside any such concern. Moreover, and of real significance, the use of the term "fresh" on, for example, a UHP juice would result in a real public health gain and benefit: consumers would have access to a product with all the attributes of a "fresh" juice and none of the potential for harm.

Most assuredly, FDA's longstanding concern over the use of the term "fresh" has never been intended to preclude the marketing of a valuable product and the application of forward-looking public health-based technologies. The appropriate focus for the agency in determining whether a product is, in fact, "fresh" continues to involve the application of the criteria contained in the existing regulation. As long as these criteria are met in the context of a product using alternative technology, the use of the term "fresh" is not only appropriate but also soundly in the public interest.

Background

a. The "Fresh" Regulation

The history of the agency's "fresh" regulation is instructive as to its intended scope and impact. Beginning in the late 1980's, FDA received a number of complaints about the deceptive use of the term "fresh" on products that were preserved by heat treatment (*e.g.*, canned pasta sauce) and on products that had been concentrated and reconstituted (*e.g.*, fruit juices). 56 Fed. Reg. 60421, 60463 (November 27, 1991). The result of these marketing initiatives, as confirmed by the Institute of Medicine ("IOM") in its 1990 report, "Nutrition Labeling, Issues and Directions for the 1990's," was the potential for consumer confusion and deception. The IOM, thus, recommended that terms like "fresh" be controlled by specifying the conditions for their use.

The standard formally adopted by the agency to describe the appropriate contours of the use of the term "fresh" was that which had been employed by FDA on a rather informal but, nevertheless, longstanding basis since the 1940's. The standard was essentially -- and remains -- that the use of the term "fresh" on foods that have been frozen or subjected to heat or chemical processing (for example, canning, cooking, pasteurization, smoking or use of a preservative) is, simply put, false and misleading within the meaning of Sections 403(a)(1) and 201(n) of the Food, Drug and Cosmetic Act (the "Act"). *See* 56 Fed. Reg. at 60463.

Thus, in simplest terms the "fresh" regulation did not break new ground in the agency's understanding of what constituted a "fresh" product. For example, both before and after the regulation FDA would reasonably view a food like pasteurized orange juice as not "fresh." The regulation did provide, however, the agency with something it had never had before: a regulation to assist the agency in efficiently eliminating from the market clearly false and misleading labeling representations suggesting that a heat treated or chemically preserved product was somehow, nevertheless, "fresh."

The regulation exempts from its purview any use of the term "fresh" that does not suggest or imply that a food is unprocessed or unpreserved. The regulation goes on to provide that the use of the term "fresh" in a manner that suggests or implies that the food is "unprocessed" means that the food is in its raw state, has not been frozen or subjected to any form of thermal processing, and has not been subjected to any other form of preservation. Explaining this position, the regulation provides that the use of the term "fresh" to describe pasteurized whole milk does not imply that milk is unprocessed

because consumers know and commonly understand that milk is nearly always pasteurized. Similarly, as explained in the preamble to the final rule, the term "fresh" as used on bread does not imply that the food is unprocessed and in its raw state. *See* 58 Fed. Reg. 2302, 2403 (January 6, 1993). Thus, where consumers have reason to understand that a food has, in fact, been processed, the use of the term "fresh" does not necessarily or automatically invoke Section 101.95 or the misbranding provisions of the Act. Where, however, the use of "fresh" suggests or implies to consumers that the food is unprocessed or unpreserved, the "fresh" regulation requires that the food has not been subjected to freezing or any form of thermal processing or "any other form of preservation" except as permitted by paragraph (c) of the regulation.

The exceptions provided by paragraph (c) are significant in that their existence makes clear that the "fresh" regulation does not bar the use of "fresh" under all circumstances in which a food has been subjected to non-thermal treatment. To the contrary, the regulation permits the use of "fresh" even though a food has been subjected to irradiation, pesticide application, chlorine or acid washes, waxing or coating and refrigeration.

b. UH Technology and Orange Juice, in General

Ultra high pressure technology can subject a product like orange juice to pressures of 60,000 psi and higher for a specified period of time. This pressure kills harmful microorganisms (by an eight log reduction) but does not alter the sensory and nutritional characteristics of the treated juice. Although juice subjected to UHP technology experiences a slight increase in temperature, this slight increase has no effect on the characteristics of the food. Moreover, the temperature change is reversed when the pressure is released. And, the enzymes in orange juice subject to UHP are not deactivated. In sum, there is nothing that alters the fundamental sensory, compositional, or nutritional attributes of an orange juice produced using UHP.

Consumer and Industry Understanding of "Fresh" In Light of Section 101.95

a. In the Context of a Food Like Orange Juice, "Fresh" does not Categorically Suggest "Unprocessed" or "Unreserved"

Consumers clearly have reason to understand that all "fresh" juices have been "processed" to a certain degree. Indeed, juices do not exist in nature separate from fruit. Rather they are produced by expression or extraction (*see*, for example, 21 C.F.R. § 145.3(j)) followed by refinement of the liquid phase of solid fruit and then packaged. Similarly, activities carried out to package citrus juices into saleable portions, whether for consumer or industrial use, are also processing. Even the term commonly used to describe fresh juices, "fresh-squeezed," indicates a process. These processes all have one thing in common: they have no meaningful impact on the sensory or nutritional characteristics of the "processed" food and, thus, have no impact on the consumer's notion of "freshness." A technology like UHP is comparable to these processes and is substantially different from the types of heat and chemical treatments that suggest to consumers that a food has been processed or preserved in such a way as to meaningfully alter the sensory or nutritional makeup of the food. This focus on the attributes of the end product (which could include a "quantitative" focus on nutrients, naturally occurring flavorants, etc.) seems to us to be a critical consideration in evaluating whether an alternative technology food can appropriately and non-misleadingly bear the "fresh" appellation.

b. An Alternative Technology Product Like UHP Orange Juice is Non-thermally Processed

Even if "fresh" when applied to an orange juice produced using UHP or comparable technology were to suggest unprocessed and unpreserved, the product could still be labeled "fresh." FDA regulations view "unprocessed" as connoting raw or uncooked. Section 101.95(a).[2] Whereas cooking is generally understood to involve the

[2] FDA reiterated this position most recently in an April 3, 1998 letter from Elizabeth J. Campbell to William J. Spain of Del Monte Foods Corporation concerning the use of FreshCut as a trademark for canned fruits and vegetables. Dr. Campbell wrote that fresh ingredients are *"raw ingredients* that have not been frozen, dried, chemically treated or subjected to any form of thermal processing or preservation prior to the packaging process" (emphasis added).

application of heat, UHP technology involves the application of pressure. Simply put, orange juice produced using a technology like UHP remains raw and uncooked.

The regulation also speaks of "any form of thermal processing." The scope of the term "thermal processing " is suggested by the FDA's juice HACCP proposal:

> The NACMCF [the National Advisory Committee on Microbiological Criteria for Foods] . . . stated that traditional heat treatments given to juice and juice products have been designed to achieve shelf stability, to remove water (*i.e.*, concentration), or to affect other quality-related factors, and that these treatments, commonly referred to as "pasteurization," are greatly in excess of a process needed to inactivate foodborne pathogens.

63 Fed. Reg. 20449, 20453 (April 24,1998). UHP technology, as well as many other alternative technologies, does not rely upon heat to achieve its effect.

c. An Alternative Technology Product Like A UHP Juice Is Not Subject to a Form of Preservation

FDA regulations require that "fresh" foods not have been subjected to any other form of preservation. Section 101.95(a). The preamble to the final rule suggests the scope of this concept:

> [T]he agency does not agree that the use of the term "fresh" is appropriate if a food has been subjected to chemical treatments, including but not limited to antioxidants, antimicrobial agents, or preservatives, that introduce chemically active substances that remain in or on the food to preserve or otherwise affect the food.

58 Fed. Reg. at 2403. Similarly, the language of 21 C.F.R. §§ 170.3(o)(2) and (3) suggests that "preservatives" are antimicrobial agents added to food. (*See also* 21 C.F.R. §§ 170.3 (o) (2) and (3), which discuss preservation as the addition of chemicals.) Moreover, the standards of identity for lemon juice and grapefruit juice (21 C.F.R. §§ 146.114 and 132) indicate that juice can also be "preserved" by "heat sterilization (canning), refrigeration, [or] freezing."

A technology like UHP involves no addition of chemical substances to the juice, no heat treatment and no freezing.[3] UHP technology does not act as an antimicrobial agent or preservative that introduces active substances in the food to preserve and retard deterioration. Rather UHP technology kills microbes which are introduced through surface contamination from the surrounding environment. This so-called "kill" step involves a refinement in juice extraction and is equivalent to the expression of juice from sterile fruit in a sterile environment. The beneficial aspect of this type of technology can, thus, be simply viewed as accomplishing the same thing as sterilizing the surface of the fruit and then preparing juice in a germ-free environment: it allows the juice to reach its natural shelf-life rather than to spoil due to the effect of external microbiological contamination. Simply put, a UHP or comparable technology fosters the natural shelf-life that would be expected from juice that contains no external contaminants. This is not the same as what is commonly understood -- by FDA or by consumers -- to be "preservation."

The conclusion that a UHP-type treatment does not constitute a "form of preservation" is further reinforced by comparing it to the types of treatment that, under Section 101.95(c)(1), do not preclude the use of "fresh." Paragraph (c) permits the use of the term "fresh" to describe a raw food that has been treated

- with ionizing radiation up to a dose of 1 kiloGray;
- by the post-harvest use of approved pesticides;
- by the application of a mild chlorine or acid wash;
- by the application of approved waxes or coatings.

The discussion in the preamble of the irradiation exception reveals why such treatments do not preclude the use of "fresh:"

> The *test* for determining the appropriateness of applying the term "fresh" to foods treated with post harvest applications, including treatment with low dose irradiation, *is the effect*

[3] Although UHP-treated juices can be refrigerated, Section 101.95(c)(2) states that the refrigeration of a food does not preclude use of the term "fresh."

> *that the process has on a food* ... Exposure of raw foods to low dose radiation typically causes *insignificant changes in their appearance and nutrient content*....
>
> The agency is not aware of any information that suggests that low dose ... irradiation of raw foods *causes adverse changes in their physical or sensory qualities that would affect consumers' perceptions as to whether they are raw.* Therefore, in the absence of meaningful differences in the *appearance and quality* between pre- and post- irradiated foods and in light of the requirement that irradiated foods must be clearly labeled as such, the agency believes that it is appropriate to provide that the term "fresh" may be used to describe [such] foods.

58 Fed. Reg. at 2404 (emphasis added). Like irradiation, UHP technology, for example, causes no meaningful or noticeable change in the appearance, taste and nutrient content of a juice. As a result, UHP technology, as a case in point, causes no adverse changes in the physical or sensory qualities of a juice that would affect consumers' perceptions as to whether that juice is "fresh." This, as we noted above, is in our view a reasonable, understandable and practical way to assess and ensure that a food subject to a technology like UHP remains "fresh."

The agency relied upon precisely the above rationale in issuing a March 6, 1996 opinion letter concerning the propriety of labeling as "raw" oysters that had been subjected to a mild form of heat treatment to eliminate the harmful microorganism *Vibrio vulnificus*. In issuing its opinion the agency focused not on the treatment method but rather on its effect, i.e., that the oysters retained the organoleptic qualities associated with such a raw product. A UHP orange juice is even more "fresh" than such oysters for it undergoes no heat treatment whatsoever.

d. Summary: As the UHP Experience Reveals, An Alternative Technology Food Can, Depending on the Circumstances, Be "Fresh"

The "fresh" regulation reasonably sets forth what *cannot* be done to foods that are labeled fresh -- they cannot be cooked and cannot be subjected to freezing, thermal processing or any other form of preservation. Consumers and industry understand these

criteria. In this context, a technology like UHP technology is a major technological advance not only because of what it does to juice, but also because of what it *does not* do to juice.

Moreover, a technology like UHP is not a thermal process. UHP kills microorganisms in juice by subjecting them to high pressure for a short period of time. And, the pressure does not alter the sensory and nutritional characteristics of the juice --a key measure of "freshness." Thus, UHP technology differs significantly from pasteurization or other thermal processing. Also, it does not involve freezing.

A technology like UHP does not chemically or artificially preserve juice. Preservatives are generally regarded as treatments that introduce chemically active substances that remain in or on the food to preserve or otherwise affect the food or as thermal processing or freezing. With UHP technology, however, nothing is added to the juice and, as explained above, the technology simply provides the normal shelf-life a juice would be expected to have if the external microbial contaminants of the raw fruit were removed before processing.

An alternative technology food can, thus, be "fresh." It can meet the criteria that have been established and used now for years for such foods. For consumers, it can have all the sensory and nutritional attributes of any other "fresh" food. To suggest that another whole line of terminology be employed to describe the product simply because a new technology has been applied is not only unnecessary but also inconsistent with Section 101.95. Such an approach would also be at odds with Sections 403(a) and 201(n) of the Act in that it would likely mislead consumers into concluding, wrongly, that a meaningful difference in freshness exists between, for example, a "fresh" UHP juice and other juice products meeting the definition of "fresh" simply because a new technology has been employed.[4] Moreover, taking the extraordinary (and unnecessary) step of attempting to require labeling concerning the use of alternative terminology could be

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[4] As noted above, a key attribute of the present rule is that it defines "fresh" by describing certain things that *cannot* be done to food that is labeled as "fresh," such as, e.g., heat-treatment, freezing, and chemical preservation. It then lists various treats that *do not* preclude the use of the term "fresh," such as, e.g., radiation or the use of an acid wash, pesticide, or wax coating. If any change is considered to the existing regulation, it should focus on making clear that the identified treatments do not preclude the use of "fresh" but rather are merely *examples* of such treatments. This will foster opportunities and incentive for designing a new technology that will not preclude the use of "fresh" and that will protect public health.

misinterpreted by consumers as a warning about or as a reason to fear the use of new safety-enhancing technology -- the agency has a long history of avoiding the imposition on the food label of terminology that carries such potential.

Economic Considerations

Consumers have traditionally chosen to pay the premium price that accompanies "fresh" juice and "fresh" products. Consumers expect that such products will deliver all the attributes of "freshness" with sensory and nutritional attributes being the most reliable indicators. If anything, the advent of new technologies may result in more competitively priced "fresh" products.

Conclusion

The use of a new technology to improve the safety of a food does not, in and of itself, preclude the product from being "fresh" within the meaning of Section 101.95. As such, the regulation provides a beneficial incentive to develop a product like a UHP juice which bears all the sensory and nutritional characteristics of fresh-squeezed juice but none of the harmful pathogens that can be present in such juice. Without question, the development of such "fresh" products would enhance public health protection and further the administration's goal of reducing microbial risks from food.

Sincerely,

Fred H. Degnan

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